

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4426. Misbranding of suprarenal concentrate capsules and yellow bone marrow concentrate. U. S. v. 213 Bottles, etc. (F. D. C. No. 36512. Sample Nos. 37528-L, 37529-L.)

LIBEL FILED: April 20, 1954, District of New Jersey.

ALLEGED SHIPMENT: On or about December 2, 1953, and January 20 and February 16, 1954, by the Armour Laboratories, from Bradley, Ill.

PRODUCT: 213 bottles of *suprarenal concentrate capsules* and 90 bottles of *yellow bone marrow concentrate* at East Paterson, N. J.

LABEL, IN PART: (Bottle) "100—2 Grain Suprarenal Concentrate Capsules Each Capsule Contains The Powdered Concentrate Derived From 15 Grains Of Fresh Suprarenal Glands Relatively Free From Epinephrine. The Armour Laboratories * * * Chicago 11, Ill." and "Armour Laboratories 100 Glanules Y. B. M. Yellow Bone Marrow Concentrate * * * Indications: Mild Chronic Agranulocytosis Due To Infection Or The Toxic Action Of Drugs * * * Each Glanule Contains 21 Milligrams of Nonsaponifiable Material Derived From 12.5 Grams Of Fresh Yellow Bone Marrow."

NATURE OF CHARGE: *Yellow bone marrow concentrate.* Misbranding, Section 502 (a), certain statements on the bottle label and in a brochure attached to each bottle of the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for chronic agranulocytosis and leukopenia. The article was not an adequate and effective treatment for such conditions.

Suprarenal concentrate capsules. Misbranding, Section 503 (b) (4), the article was a drug to which Section 503 (b) (1) did not apply, and its label bore the statement "Caution: Federal law prohibits dispensing without prescription."

Further misbranding, Section 502 (f) (1), the labeling of the *yellow bone marrow concentrate* and the *suprarenal concentrate capsules* failed to bear adequate directions for use, and these articles were not entitled to any exemption from such requirement.

DISPOSITION: June 2, 1954. Default decree of condemnation and destruction.

4427. Misbranding of Mona-Serts vaginal tablets. U. S. v. 1,992 Boxes * * *. (F. D. C. No. 36812. Sample No. 86230-L.)

LIBEL FILED: May 28, 1954, Western District of Kentucky.

ALLEGED SHIPMENT: On or about June 1, 1952, by Strong, Cobb & Co., Inc., from Cleveland, Ohio.

PRODUCT: 1,992 boxes of *Mona-Serts vaginal tablets* at Louisville, Ky., in possession of the Wintersmith Chemical Co., Inc. A leaflet entitled "Mona-Serts Vaginal Tablets" was enclosed in each box.

RESULTS OF INVESTIGATION: In addition to the leaflet enclosed in each box, a number of leaflets entitled "Mona-Serts Vaginal Tablets Antiseptic—Fungicidal" had been printed locally for the consignee and were in his possession.

LABEL, IN PART: (Box) "24 Tablets Mona-Serts Vaginal Tablets Antiseptic—Fungicidal For the treatment of vaginal infections Each tablet contains: Aluminum Caprylate. . . . 3 grs. Phenylmercuric Acetate. . . . 0.3 mg. Urea. . . . 1.0 gr. In combination with Citric Acid, Boric Acid, Lactose and Dextrose."